Roberts, D. L., F. J. Romay, V. A. Marple, "Nozzle Examination Methods for the Next Generation Pharmaceutical Impactor," presented at Drug Delivery to the Lungs XII, The Aerosol Society, London, UK, December 13, 2001.

User Experience

- Leung, K., E. Louca, M. Gray, G. Tipples, A. L. Coates, "Use of the Next Generation Pharmaceutical Impactor for Particle Size Distribution Measurements of Live Viral Aerosol Vaccines," <u>J. Aerosol Med.</u>, <u>18</u>, 414-26 (2005).
- Williams, R., A. Sleep, T. Morris, "Next Generation Impactor: Practical Experience of Development and Validation of Metered-Dose Inhaler Methods," Drug Delivery to the Lung XV, The Aerosol Society, London, UK, December 9-10, 2004, pg. 166-69.
- 3. Beighton, J., A. Majid, L. Wojnarowicz, "The Determination of Aerodynamic Particle Size Distribution from a Metered-Dose Inhaler Using the Next Generation Impactor," Drug Delivery to the Lung XV, The Aerosol Society, London, UK, December 9-10, 2004, pg. 252-55.
- 4. Mitchell, J. P., "The Next Generation Impactor (NGI): Results from the Evaluation of Prototype Instruments with pMDI-Based Formulations," presented at Drug Delivery to the Lung XI, London, England, December 11-12, 2000.
- Shrubb, I. T., "The Next Generation Impactor (NGI): Results from the Evaluation of Prototype Instruments with DPI-Based Formulations," presented at Drug Delivery to the Lung XI, London, England, December 11-12, 2000.

Comparisons to Other Sizing Methods

Myrdal, P. B., E. Mogalian, J. P. Mitchell, M. Nagel, C. Wright, B. Kiser, M. Prell, M. Woessner, S. W. Stein, "Application of Heated Inlet Extensions to the TSI 3306/3321 System: Comparison with the Andersen Cascade Impactor and Next Generation Impactor," J. Aerosol Med., 19, 533-42 (2006).

- 2. Kusmartseva, O., P. R. Smith, D. Morton, "Comparing In-Line Optical and NGI Measurements on a Drug Cloud," Drug Delivery to the Lung XV, The Aerosol Society, London, UK, December 9-10, 2004, pg. 183-86.
- 3. Kamiya, A., M. Sakagami, M. Hindle, P. R. Byron, "Aerodynamic Sizing of Metered Dose Inhalers: An Evaluation of the Andersen and Next Generation Pharmaceutical Impactors and Their USP Methods," <u>J. Pharm. Sci.</u>, <u>93</u>(7), 1828-37 (2004).
- Mitchell, J. P., M. W. Nagel, K. J. Wiersema, C. C. Doyle, "Aerodynamic Particle Size Analysis of Aerosols from Pressurized Metered-Dose Inhalers," <u>Pharm. Sci. Tech.</u>, 4, article 54, 2003.

Simple or Semi-Automatic Tools for Drug Recovery from the NGI

- Roberts, W. L., P. W. Waters, H. Mohammed, R. Williams, B. Gillet, "A Semi-Automated Sample Recovery System for the Next Generation Pharmaceutical Impactor," Respiratory Drug Delivery 2006, Boca Raton, Florida, April 23-27, 2006.
- 2. Gibbison, F., R. Manley, A. D. Cooper, "Evaluation of the Gentle Rocker as a Laboratory Aid for Fine Particle Dose Determination," Academy of Pharmaceutical Sciences, Bath, UK, March 27-28, 2007.
- 3. Fransson, K., M. Persson, M. Svensson, "Sample Preparation Tools for the Next Generation Pharmaceutical Impactor," Drug Delivery to the Lung XII, Aerosol Society, London, England, December 13-14, 2001.

Appendix A

Major Parts for the Next Generation Pharmaceutical Impactor

This appendix shows each of the parts of the impactor.



Figure A-1 - Top Side of NGI Lid

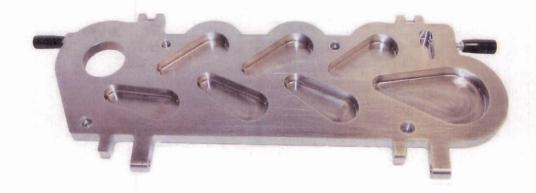


Figure A-2 - Bottom Side of NGI Lid Showing the Interstage Passageways



Figure A-3 - Top Side of NGI Seal Body with Nozzles and O-Rings



Figure A-4 – The Eight Nozzle Pieces of the NGI



Figure A-5 – Interference Fit of Nozzle Pieces into Seal Body

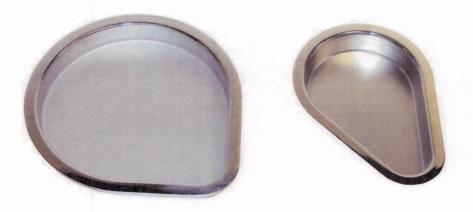


Figure A-6 – One Large Cup (L) and One Standard Cup (R) – Six Standard Cups and Two Large Cups Comprise a Set



Figure A-7 – The Cup Tray

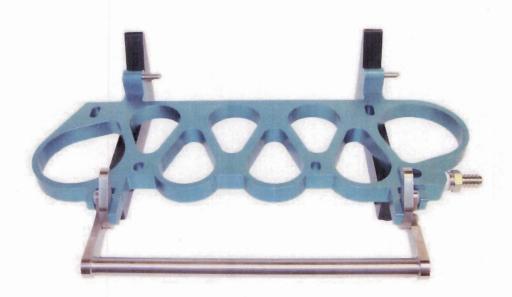


Figure A-8 - The Bottom Frame with Handle Attached

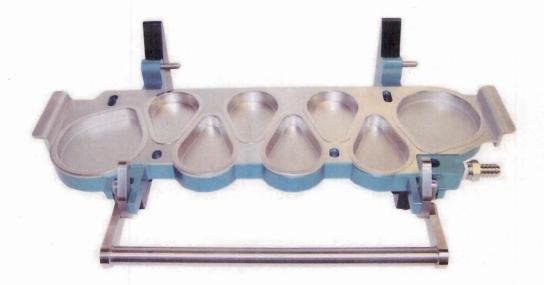


Figure A-9 - One Set of Cups in a Cup Tray on the Bottom Frame

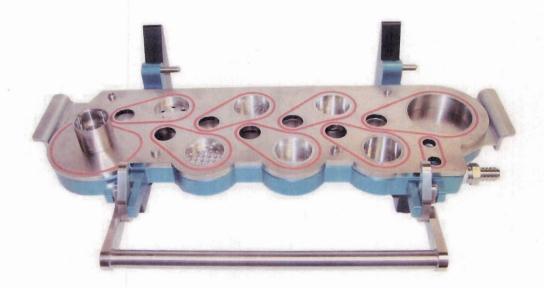


Figure A-10 - Seal Body and Cup Tray Resting on Bottom Frame

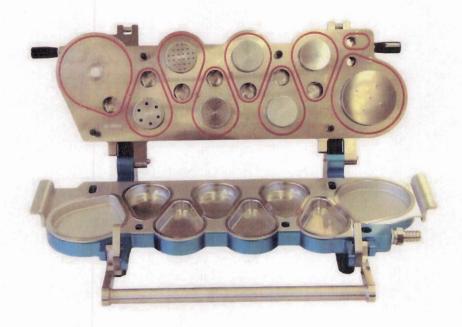


Figure A-11 – Fully Assembled Impactor in the Open Position



Figure A-12 – NGI Induction Port with Titanium Nitride Coating on Exterior Male Taper



Figure A-13 – Three-Piece Pre-Separator (L to R – Bottom, Insert, Top)

Appendix B

Accessories and Labor Saving Devices for the Next Generation Pharmaceutical Impactor



Figure B-1 - Rinsing Caps

Left – Male Taper for Induction Port and for Pre-Separator -- 0170-78-0195A-X, Center -- Face Seal for Straight End of Induction Port-- 4510-78-1042A-C, and Right -- Female Taper Plug for Pre-Separator-- 0170-01-0199A-X